UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

REBECCA NMI BARNES,

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Case No. 2:17-cv-14194

v.

HONORABLE STEPHEN J. MURPHY, III

MEDTRONIC, PLC and COVIDIEN LP,

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OPINION AND ORDER GRANTING DEFENDANTS' MOTION TO DISMISS [9]

On December 28, 2017, Defendants timely removed the case from Washtenaw County Circuit Court based on diversity jurisdiction. ECF 1. On March 19, 2018, Plaintiff filed her amended complaint. ECF 4. Plaintiff alleges four claims: (1) grossly negligent design, (2) grossly negligent manufacture, (3) breach of implied warranty, and (4) fraud based on false representation. *Id.* at 89–101. On May 7, 2018, Defendants moved to dismiss the amended complaint. ECF 9. On October 11, 2018, the Court held a hearing on the motion. E.D. Mich. LR 7.1(f). The Court reviewed the briefs and counsels' oral arguments and will grant the motion.

BACKGROUND

In July 2014, Plaintiff Rebecca NMI Barnes had hernia repair surgery, and her surgeon implanted into her abdomen Parietex PCO mesh ("mesh implant")—a

product that Defendants manufacture, market, and distribute. See ECF 4, PgID 85–86. In March 2017, a hole developed in the mesh implant, which strangulated a reherniated section of her small intestine. Id. at 86–87. Plaintiff "underwent emergency surgery to remove" the strangulated section of her intestine. Id. at 87. During the surgery, doctors discovered that the mesh implant had adhered to Plaintiff's small intestine. Id. The surgeons removed most of the mesh implant, but some could not be removed "because it had incorporated into [Plaintiff's] anterior abdominal wall." Id. In July 2017, Plaintiff again re-herniated and underwent further surgery in November 2017. Id. The surgeons again noted problematic adhesions of the remaining mesh implant to Plaintiff's small intestine but could not remove the mesh implant without further damaging Plaintiff's intestines. Id. at 88.

STANDARD OF REVIEW

When analyzing a motion to dismiss under Civil Rule 12(b)(6), the Court views the complaint in the light most favorable to the plaintiff, presumes the truth of all well-pleaded factual assertions, and draws every reasonable inference in favor of the non-moving party. Bassett v. Nat'l Collegiate Athletic Ass'n, 528 F.3d 426, 430 (6th Cir. 2008). To survive a motion to dismiss, "the complaint must contain either direct or inferential allegations respecting all the material elements to sustain a recovery under some viable legal theory." Nat'l Hockey League Players Ass'n v. Plymouth Whalers Hockey Club, 419 F.3d 462, 468 (6th Cir. 2005) (citation omitted). It must

¹ For purposes of a motion to dismiss, the Court accepts all well-pleaded factual allegations as true. *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008). Nothing in this section constitutes a finding of fact by the Court.

allege facts "sufficient 'to raise a right to relief above the speculative level,' and to 'state a claim to relief that is plausible on its face." *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007)).

DISCUSSION

I. <u>Grossly Negligent Design Claim</u>

Plaintiff first alleges negligence under a design defect theory. See ECF 4, PgID 89–95. To succeed on a design defect claim under Michigan law, a Plaintiff must demonstrate that "(1) the product was not reasonably safe when it left the control of the manufacturer; and (2) a 'feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users." Croskey v. BMW of N. Am., Inc., 532 F.3d 511, 516 (6th Cir. 2008) (quoting Mich. Comp. Laws § 600.2946(2)). Defendants argue that Plaintiff failed to plead that a feasible alternative production practice was available to Defendants that would have prevented Plaintiff's harm. ECF 9, PgID 160–62. Plaintiff counters that she pleaded three feasible alternatives to Defendants' Parietex PCO mesh—(1) the Shouldice surgical procedure, (2) biologic mesh, and (3) polypropylene mesh. ECF 11, PgID 179.

The Michigan Supreme Court has not addressed when a proposed alternative is a different product rather than a feasible alternative production practice. But several other jurisdictions have addressed when a proposed alternative is too far

removed from the challenged product to constitute an alternative design.² See Hosford v. BRK Brands, Inc., 223 So. 3d 199, 205–08 (Ala. 2016) (collecting cases). In jurisdictions requiring plaintiffs to prove the existence of a safer alternative design, "a design for a different, albeit similar, product" will not suffice, "even if it serves the same purpose." Id. at 208.

The Alabama Supreme Court found that a design defect claim premised on the theory that all ionization smoke alarms are unsafe and that dual-sensor smoke alarms are a safer alternative design failed as a matter of law because the two types of smoke alarms are different products—even though they serve the same purpose and are similar. *Id.* Similarly, the Texas Court of Appeals held that a design defect theory proposing estrogen alone as a safer alternative design to a drug that combined estrogen and progestin failed as a matter of law because "Texas law does not recognize [that] sort of categorical attack on a product." *Brockert v. Wyeth Pharm., Inc.* 287 S.W.3d 760, 771 (Tex. App. 2009). The Fifth Circuit, applying Louisiana law, held that "other products that do not use pedicle screws . . . such as external neck braces or internal systems that use hooks or wires" are not alternative designs to pedicle screws even though they treat the same ailment. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999). There, the Fifth Circuit noted that:

[u]nderlying this argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be

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² Although Mich. Comp. Laws § 600.2946(2) uses the phrase "alternative production practice," cases analyzing design defect claims under Michigan law use "alternative production practice" and "alternative design" interchangeably. *See, e.g., Croskey*, 532 F.3d at 516 (citing the statutory language and then using "alternative design" when elaborating on what the statute requires a plaintiff to prove).

an acceptable product. The problem with this argument is that it really takes issue with the choice of treatment made by [the plaintiff's] physician, not with a specific fault of the pedicle screw sold by [the defendant].

Id.

Plaintiff's theory alleges that all polyester hernia meshes are unacceptable. Her proposed alternatives are alternative treatment methods or alternative types of mesh, not alternative production practices or designs for polyester hernia mesh. The Shouldice technique is a technique for treating hernias that does not involve any mesh. ECF 4, PgID 93. Biologic mesh is another type of mesh that can be used in hernia repairs and is made out of "bovine, porcine, or human cadaver dermis." *Id.* at 92. Polypropylene mesh is a different type of synthetic mesh than polyester mesh. *Id.* at 93. As with ionization smoke alarms, drugs that combine estrogen and progestin, and pedicle screws, Plaintiff's design defect claim cannot succeed by categorically challenging the safety of polyester mesh and pleading only alternative categories of products as alternative production practices. Taking Plaintiff's allegations as true, she has not alleged an alternative production practice for Defendants' product—only alternative *products*, which are insufficient as a matter of law to establish a design defect claim. The Court will therefore dismiss Plaintiff's design defect claim.

II. Grossly Negligent Manufacture and Breach of Implied Warranty Claims

Plaintiff next alleges negligence under a manufacturing defect theory and breach of an implied warranty. ECF 4, PgID 95–99. An integral element of each claim is "a defect attributable to the manufacturer." *Caldwell v. Fox*, 394 Mich. 401, 410 (1975) (quoting *Piercefield v. Remington Arms Co.*, 375 Mich. 85, 98–99 (1965)). Here,

Plaintiff fails to allege facts sufficient to raise above a speculative level a claim that the defect in her mesh implant was attributable to the manufacturer. Plaintiff simply alleges that the Court can infer that the defect is attributable to the manufacturer because it was implanted in Plaintiff's abdomen where no one could access it. ECF 4, PgID 97 (quoting *Kenkel v. Stanley Works*, 256 Mich. App. 548, 560 (2003)).³ But the theory Plaintiff relies on is inapplicable.

In *Kenkel*, the plaintiff was injured by an automatic door and presented evidence that a defect in the door's circuitry caused her injuries. 256 Mich. App. at 561. And in *Holloway v. Gen. Motors Corp. Chevrolet Div.*, 403 Mich. 614 (1978)—the original source of Plaintiff's quote—a break in the ball joint of a vehicle caused the plaintiff's injuries. In both cases, Michigan courts permitted an inference that the defect was attributable to the manufacturer because the alleged defect was in a part of the product that no person could readily access after the product left the control of the manufacturer.

Here, however, the alleged defect is a hole in Plaintiff's mesh implant. Plaintiff alleges that "Parietex PCO mesh is a single-use medical device that Defendants manufacture, import, and deliver to hospitals in a sealed, sterile packaging" and that "Parietex PCO has no user-serviceable parts, requires no maintenance, and is totally inaccessible to the patient after implantation." ECF 4, PgID 96. But she neglects to account for the gap between the two steps. The manufacturer did not implant the mesh into Plaintiff's abdomen. At least one surgeon had to open the sealed, sterile

³ The quoted language actually comes from 256 Mich. App. 548, **559** (2003).

packaging and implant the mesh into Plaintiff's abdomen. And, as Plaintiff notes,

"sutures or tacks [are] used to affix the edges of the mesh." Id. at 91. Because another

actor—the surgeon—could easily have affected the integrity of the mesh implant after

it left the control of the manufacturer, the Court cannot infer that the defect that

caused Plaintiff's injury is attributable to Defendants. The Court will therefore

dismiss Plaintiff's manufacturing defect and breach of implied warranty claims.

III. Fraud Based on False Representation Claim

Plaintiff lastly alleges fraud based on false representation. But Plaintiff

concedes that she failed to adequately plead her fraud claim. ECF 11, PgID 189. The

Court will therefore dismiss Plaintiff's fraud claim.

IV. Conclusion

Because Plaintiff did not plead facts sufficient to raise her right to relief above

the speculative level on any claim, the Court will grant Defendants' motion to dismiss

and will dismiss the case.

WHEREFORE, it is hereby ORDERED that Defendants' motion to dismiss

[9] is **GRANTED**.

IT IS FURTHER ORDERED that the case is DISMISSED.

SO ORDERED.

s/Stephen J. Murphy, III STEPHEN J. MURPHY, III

United States District Judge

Dated: March 26, 2019

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on March 26, 2019, by electronic and/or ordinary mail.

s/David P. Parker Case Manager